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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,422	12/16/2003	Steven M. Martin	UOM 0282 PUSP	6326

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EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	PAPER NUMBER
1743	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/737,422	MARTIN ET AL.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-29 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 3/22/04, 5/9/06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 6, 10-12, 14-17, 20, 24-25 and 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosemberg et al (WO 99/47907).

Rosemberg et al teach of a device for determining the clotting time of a blood sample by either capacitance or resistance. The device 10 comprises a sensor 12 having an inlet port 14 into which a blood sample is placed. The blood sample is drawn into a test chamber 16 formed between two electrodes 18 by capillary action. Preferably, the test chamber 16 is a single capillary channel. The sensor 12 is a single-use disposable sensor for easy cleaning and maintenance of the device 10. The electrodes 18 may be placed either on the outer or inner walls of the test chamber 16. However, when the electrodes 18 are located on the inner walls, they are insulated from contact with the blood sample by an insulator 21. The sensor 12 is in electrical

contact with a capacitance measurement circuit 25 that serves as a signal processor for processing signals obtained by the electrodes 18. The capacitance measurement circuit 25 is attached to both electrodes 22, 24 on the sensor 12. The electrodes 18 are disposed in parallel on opposing sides of the test chamber 16, and either extend along the length of the test chamber 16, or are relatively short so as to extend only along a portion of the walls 19 of the test chamber 16. The electrodes are made from conductive metal or carbon traces such as a mixture of silver and silver chloride. The device further comprises a cover or cap for covering the test chamber, wherein the cover has at least one aperture therein serving as an inlet port. The test chamber can be present on a disposable plastic substrate to which the cover is attached. In a method of using the device taught by Rosemberg et al, a blood sample is applied to the inlet port 14 of the device, and the blood flows through the test chamber 16 by capillary action. The blood flows between the electrodes 18, causing an increase of the electrical capacitance between the first electrode 22 and the second electrode 24. The clotting time of the blood is determined either by determining when the cessation of blood flow through the test chamber 16 has occurred, as noted by measuring the time point at which the amount of capacitance reaches a maximal value, or by measuring the capacitance at a fixed time point, after a predetermined period of time has elapsed from the time at which the sensor 12 was placed in contact with the capacitance measurement circuit 25. After measuring the capacitance, a meter 29 converts the measured signal into a digital signal by a converter 30. The digital signal is then sent to a processor 32 for analysis and calculation of the clotting time. Processor 32 contains instructions for calculating the clotting time from the signal. Rosemberg et al also teach that resistance can be used to measure the

clotting time of a sample in place of capacitance. See Figures 1-2D, and pages 6-12 and 15-22 in Rosemberg et al.

4. Claims 1-29 are rejected under 35 U.S.C. 102(a) as being anticipated by Martin et al (article entitled "A Microsystem for Near-Patient Accelerated Clotting Time Blood Test" published at the 39th Design Automation Conference, June 10-14).

Martin et al teach of a microsystem and device for determining the clotting time of blood substantially as recited in instant claims 1-29. The paper describes an integrated sensor for blood coagulation time measurement that consists of a flow channel and read-out circuitry. The device is intended for a single use, and contains a microfluidic channel therein in the shape of a spiral loop. A drop of blood is placed on the device, and is wicked into the capillary loop where resistance constantly changes as the blood enters. An analog circuit measures the resistance. When the resistance becomes constant, a signal indicates that the sample blood has clotted. This article to Martin et al contains a different inventive entity than the instant application since inventor Robert K. Franklin is not named as an author of the article. Therefore, this article qualifies as prior under 35 USC 102(a). It is also noted that this article was cited as an anticipatory reference (X) in the search report for the corresponding PCT application (PCT/US03/40335). The Examiner made an exhaustive attempt to locate a copy of this article, but was unable to do so. Therefore, since Applicants are presumed to be aware of this reference from the PCT search report and in possession of a copy of this reference, Applicants are requested to file a copy of this article in an Information Disclosure Statement so that it can be properly made of record in the application.

5. Claims 1-3, 5-8, 10-17, 19-22 and 24-29 are rejected under 35 U.S.C. 102(a) as being anticipated by Richter et al (WO 02/050534).

Richter et al teach of a device for measuring blood coagulation and a method thereof. The device comprises a disposable test strip 100 comprising an upper and lower support 101, 103. A microchannel 102 is formed into the upper surface of the lower support member 103. A second substrate layer 101 is laminated on top of the support member 103, thereby closing the open microchannel 102. Electrodes 104 are formed either on the respective outer surfaces of the substrate layers or on the inner surfaces of the microchannel 102 so a to be at least partially in fluid communication with the channel. See Figures 1 and 2 in Richter et al. A sample inlet port 106 serves to introduce a blood sample into the device. The inlet is substantially level with the microchannel and the sample reservoir fills by capillary action. The electrodes can either extend along the length of the microchannel or a portion thereof, or can be present at spaced intervals along the length of the channel. The electrodes can be made from any inert conductor material such as carbon, gold or platinum. In the embodiment depicted in Figure 3, the microchannel 202 is spiral shaped in order than an increased length can be achieved for a given surface area of the device. In use, the test strip is inserted into a meter such that the electrodes on the meter form an electrical connection with corresponding contacts provided within the meter. A sample of blood is then applied to the end of the microchannel 102 which will flow along the microchannel, and simultaneously a timer is started and measurement is commenced. Alternatively, a sample can be drawn initially into a reservoir via the inlet port whereby fill-detector electrodes will determine whether enough sample has been applied. A flow controlling means will then allow the sample to be drawn into and along the microchannel under capillary action. The flow

controlling means is activated by the fill-detection means such that the device requires no further input from the user. The fill-detection electrodes can also serve as a switch to turn on the device. As the blood flows along the microchannel, coagulation of the blood eventually arrests the flow of blood partway along the channel. The two electrodes 101 and 102 are connected to a measurement circuit (i.e. signal processor) via connections 106 at the edge of the strip. This circuit is used to measure the capacitance between the two electrodes. As the blood flows through the channel, the capacitance between the two electrodes will change. A measurement is made when the flow of fluid has stopped or when the rate of change falls to within a predetermined value. See Figures 1-3 and pages 6-10, 16-19 and 22 of Richter et al.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 4, 9, 18 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richter et al (WO 02/050534). For a teaching of Richter et al, see previous paragraphs in this Office action.

Richter et al fail to teach that the electrodes can be variable spaced along the length of the channel, and that the electrodes can be spoke-shaped when the microchannel is in the form of a spiral. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to variably space the electrodes along the microchannel in the device taught by Richter et al so as to help increase the resolution of the capacitance measurement. It also would have been obvious to one of ordinary skill in the art to provide the electrodes in the device taught by Richter et al in the shape of spokes when the microchannel is in the form of a spiral so as to allow maximum contact between the electrodes and the multiple portions of the spiral-shaped channel with a minimum use of electrode materials.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: WO 2004/059316, which is the PCT application corresponding to this U.S. application; Rosemberg et al (US 7,021,122), which corresponds to WO 99/47907 described in the above paragraphs, Krulevitch et al who teach of a microfabricated impedance sensor; and Ur, Davis et al, Exner, Roussean, Hill et al, Stoner et al and Sin et al, who all teach of methods and devices for measuring blood coagulation by measuring changes in electrical impedance/capacitance in a blood sample.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

May 9, 2007

Maureen M. Wallenhorst
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GROUP [redacted] 1700